

**What is claimed is:**

1. Amniotic apoptosis modulating substances.
- 5    2. A composition with apoptosis modulating activity obtainable from human amniotic tissue prepared according to a method comprising the steps of: priming, induction, biosynthesis, and purification of the product.
- 10    3. A composition of claim 2 including lyophilizing the product.
- 15    4. A composition with apoptosis modulating activity obtainable from human amniotic tissue prepared according to a method comprising the steps of: extraction and purification of the product.
- 20    5. The composition according to claim 2, 3 and 4 further comprising a pharmaceutically effective agent.
- 25    6. The composition according to claim 5, wherein the agent is selected from the group consisting of antibiotics, wound healing agents, antioxidants, antivirals, antifungals, anti-ischemics, anti-injury, and anti-aging, immunomodulatory, anti-hypoxic, anti-toxic, 30    anti-allergic, anti-wrinkle, anti-inflammatory, anti-infectious, anti-immunogenic, and anti-neoplastic.
7. The composition according to claim 2, 3 and 4,

further comprising a physiologically acceptable carrier.

- 5        8.    The composition according to claim 7 wherein  
         the carrier is suitable for topical  
         administration.
9.    The composition according to claim 7 wherein  
         the carrier is suitable for parenteral  
10       administration.
10.   The composition according to claim 7 wherein  
         the carrier is suitable for gastrointestinal  
         administration.
- 15       11.   A composition with apoptosis modulating  
         activity derived from human amniotic tissue,  
         amnion tissue products or tissue.
- 20       12.   A composition with apoptosis modulating  
         activity produced chemically or by using  
         genetic engineering or by synthesis.
13.   The composition according to claim 11 and 12,  
25       further comprising a pharmaceutically effective  
         agent.
14.   The composition according to claim 13, wherein  
         the agent is selected from the group consisting  
30       antibiotics,       wound       healing       agents,  
         antioxidants,    antivirals,    antifungals,    anti-  
         ischemics,       anti-injury,       anti-aging,  
         immunomodulatory,    anti-hypoxic,    anti-toxic,  
         anti-allergic,    anti-wrinkle,    anti-inflammatory,

anti-infectious, anti-immunogenic, and anti-neoplastic.

- 5 15. The composition according to claim 13 and 14, further comprising a physiologically acceptable carrier.
- 10 16. The composition according to claim 15 wherein the carrier is suitable for topical administration.
- 15 17. The composition according to claim 15 wherein the carrier is suitable for parenteral administration.
18. The composition according to claim 15 wherein the carrier is suitable for gastrointestinal administration.
- 20 19. A method for producing a composition with derived from human amniotic tissue, amnion tissue products or tissue activity obtainable from human amniotic tissue comprising the steps of: priming, induction, biosynthesis, and  
25 purification.
20. A method of claim 19 including lyophilizing.
- 30 21. A method for producing a composition with apoptosis modulating activity obtainable from human amniotic tissue comprising the steps of: extraction and purification.
22. A method for producing a composition derived

from human amniotic tissue, amnion tissue products or tissue activity obtainable from amniotic tissue and/or prepared from chemical formulation, genetic engineering or synthesis.

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23. A method for improving the skin condition of a subject comprising contacting an effective amount of a composition with anti-apoptotic, anti-wrinkle, anti-aging, or anti-drying activity obtainable from human amniotic tissue with said skin surface on the subject.

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24. A method of claim 23 wherein the composition with anti-apoptotic, anti-wrinkle, anti-aging, or anti-drying activity is prepared from chemical formulation, genetic engineering or synthesis.

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25. A method for normalizing the biochemical parameters of liver function and immunologic indices in an acute viral hepatitis B subject, speeding recovery from symptoms of the disease, and preventing recurrence of the disease with an apoptosis modulating composition obtainable from human amniotic tissue by administering an effective amount of the composition to the subject.

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26. A method of claim 25 wherein the composition with apoptosis modulating activity is prepared from chemical formulation, genetic engineering or synthesis.

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27. A method of normalizing cell counts of CD3+,

CD4+, CD8+, and T-cells carrying HLA-DR antigens and improving neurological symptoms in a herpes zoster ganglioneuritis subject with an anti-apoptotic composition obtainable from human amniotic tissue by administering an effective amount of the composition to the subject.

28. A method of claim 27 wherein the composition with apoptosis modulating activity is prepared from chemical formulation, genetic engineering or synthesis.

29. A method of normalizing levels of CD3+ and CD4+ T-cell phenotypes in a diabetic peripheral polyneuropathy subject with an apoptosis modulating obtainable from human amniotic tissue by administering an effective amount of the composition to the subject.

30. A method of claim 29 wherein the composition with apoptosis modulating activity is prepared from chemical formulation, genetic engineering or synthesis.

31. A method of promoting earlier and prolonged clinical laboratory remission in a child with Idiopathic Nephropathy Syndrome (INS) and correcting the reduction in CD3+ and CDB+ T lymphocytes in the same subject with an apoptosis modulating composition obtainable from human amniotic tissue combined with prednisolone by administering an effective amount of the composition to the subject.

32. A method of claim 31 wherein the composition with apoptosis modulating activity is prepared from chemical formulation, genetic engineering or synthesis.
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33. A method of improving clinical symptoms and laboratory indices, stimulating leukocyte interferon-genesis and normalizing humoral and cellular immunity in a juvenile rheumatoid arthritis, rheumatoid arthritis or psoriatic arthritis subject with an apoptosis modulating composition obtainable from human amniotic tissue by administering an effective amount of the composition to the subject.
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34. A method of claim 33 wherein the composition with apoptosis modulating activity is prepared from chemical formulation, genetic engineering or synthesis.
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35. A method of reducing the average daily dose of oral steroid required for relief; moderately improving spirometric parameters; and increasing sensitivity to dexamethasone in a bronchial asthma subject with an apoptosis modulating composition obtainable from human amniotic tissue by administering an effective amount of the composition to the subject.
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36. A method of claim 35 wherein the composition with apoptosis modulating activity is prepared from chemical formulation, genetic engineering or synthesis.

37. A method of improving immunological indices and decreasing the frequency of infections in a pediatric patient with respiratory infection with an apoptosis modulating composition obtainable from human amniotic tissue by administering an effective amount of the composition to the subject.
38. A method of claim 37 wherein the composition with apoptosis modulating activity is prepared from chemical formulation, genetic engineering or synthesis.
39. A method of reducing allergic reactions and drug toxicity in an epileptic subject who uses anticonvulsants with an apoptosis modulating composition obtainable from human amniotic tissue by administering an effective amount of the composition to the subject.
40. A method of claim 39 wherein the composition with apoptosis modulating activity is prepared from chemical formulation, genetic engineering or synthesis.
41. A method of immunomodulation, normalizing of levels of the tumor serum marker, CA15.3, and increasing tumor-infiltrating CD5<sup>+</sup> T-cells and CD11 macrophages in an early breast cancer subject with an apoptosis modulating composition obtainable from human amniotic tissue by administering an effective amount of the composition to the subject.

42. A method of claim 41 wherein the composition  
with apoptosis modulating activity prepared  
from chemical formulation, genetic engineering  
or synthesis.
43. A method of improving clinical symptoms,  
eradicating rash, relieving pain, increasing  
activity of immunoregulatory lymphocytes and  
percentages of CD3+ and CD8 in a psoriasis  
subject with an apoptosis modulating  
composition obtainable from human amniotic  
tissue by administering an effective amount of  
the composition to the subject.
44. A method of claim 43 wherein the composition  
with apoptosis modulating activity is prepared  
from chemical formulation, genetic engineering  
or synthesis.
45. A method of treating atherosclerotic and  
other forms of vascular obstructions that cause  
ischemia of the myocardium and other tissues in  
a human subject with an apoptosis modulating  
composition obtainable from human amniotic  
tissue by administering an effective amount of  
the composition to the subject.
46. A method of claim 45 wherein the composition  
with apoptosis modulating activity is prepared  
and/or prepared from chemical formulation,  
genetic engineering or synthesis.
47. A method of limiting myocardial cell death due



to viral and immunogenic myocardioopathies with an apoptosis modulating composition obtainable from human amniotic tissue by administering an effective amount of the composition to the subject.

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48. A method of claim 47 wherein the composition with apoptosis modulating activity is prepared from chemical formulation, genetic engineering or synthesis.

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49. A method of limiting the rejection reaction that follows organ transplantation with an apoptosis modulating composition obtainable from human amniotic tissue by administering an effective amount of the composition to the subject.

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50. A method of claim 49 wherein the composition with apoptosis modulating activity is prepared from chemical formulation, genetic engineering or synthesis.

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51. A method of treating HIV infection with an apoptosis modulating composition obtainable from human amniotic tissue by administering an effective amount of the composition to the subject.

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52. A method of claim 51 wherein the composition with apoptosis modulating activity is prepared from chemical formulation, genetic engineering or synthesis.

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53. A method of treating brain ischemia and trauma with an apoptosis modulating composition obtainable from human amniotic tissue by administering an effective amount of the composition to the subject.
54. A method of claim 53 wherein the composition with apoptosis modulating activity is prepared from chemical formulation, genetic engineering or synthesis.
55. A method of treating the pathologic consequences of ischemia-reperfusion with an apoptosis modulating composition obtainable from human amniotic tissue by administering an effective amount of the composition to the subject.
56. A method of claim 55 wherein the composition with apoptosis modulating activity is prepared from chemical formulation, genetic engineering or synthesis.
57. A method of treating alcohol and morphine intoxication with an apoptosis modulating composition obtainable from human amniotic tissue by administering an effective amount of the composition to the subject.
58. A method of claim 57 wherein the composition with apoptosis modulating activity is prepared from chemical formulation, genetic engineering or synthesis.

59. A method of treating wound healing with an apoptosis modulating composition obtainable from human amniotic tissue by administering an effective amount of the composition to the subject.
60. A method of claim 59 wherein the composition with apoptosis modulating activity is prepared from chemical formulation, genetic engineering or synthesis.
61. A method of treating viral diseases with an apoptosis modulating composition obtainable from human amniotic tissue by administering an effective amount of the composition to the subject.
62. A method of claim 61 wherein the composition with apoptosis modulating activity is prepared from chemical formulation, genetic engineering or synthesis.
63. A composition with apoptosis modulating activity obtainable from human amniotic tissue having characteristic peaks as set forth in Figure 2.
64. A composition with apoptosis modulating activity obtainable from human amniotic tissue having at least one characteristic peak as set forth in Figure 2.
65. A composition with apoptosis modulating activity obtainable from human amniotic tissue

having characteristic peaks as set forth in Figure 3.

- 5 66. A composition with apoptosis modulating activity obtainable from human amniotic tissue having at least one characteristic peak as set forth in Figure 3.
- 10 67. A method for protecting cardiomyocytes from injury, comprising contacting said cardiomyocytes with an effective amount of the composition of claim 65.
- 15 68. A method for protecting cardiomyocytes in a subject comprising administering to the subject an effective amount of the composition of claim 65 to said subject.
- 20 69. The method of claim 67 or 68, wherein the cardiomyocyte is chemically injured.
- 25 70. A composition capable of inhibiting or killing cancer cells, wherein said composition is obtainable from human amniotic tissue with apoptosis modulating activity.
- 30 71. A method of inhibiting or killing cancer cells comprising contacting said cancer cells with an effective amount of claim 70.
72. A method of inhibiting or killing cancer cells comprising administering to the subject an effective amount of the composition of claim 68 to said subject.

- 5 73. A composition which is antagonistic to H1-histamine receptor, wherein said composition is obtainable from human amniotic tissue with apoptosis modulating activity.
- 10 74. A method to produce effects which are antagonistic to H1-histamine receptor in a cell, comprising contacting said cell with an effective amount of the composition of claim 73.
- 15 75. A method to produce effects which are antagonistic to H1-histamine receptor in a subject comprising administering to the subject an effective amount of the composition of claim 73 to said subject.
- 20 76. A composition which is inhibitory to A2-phospholipase activity, wherein said composition is obtainable from human amniotic tissue with apoptosis modulating activity.
- 25 77. A method for producing inhibitory A2-phospholipase activity in a cell comprising contacting said cells with an effective amount of the composition of claim 76.
- 30 78. A method for producing inhibitory A2-phospholipase activity in a subject comprising administering to the subject an effective amount of the composition of claim 76 to said subject.

79. A composition for protecting cardiomyocytes, wherein said composition is obtainable from human amniotic tissue with apoptosis modulating activity.

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80. A method for protecting cardiomyocytes in a cell comprising contacting said cell with an effective amount of the composition of claim 79.

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81. A method for protecting cardiomyocytes in a subject comprising administering to the subject an effective amount of the composition of claim 79 to said subject.

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82. A composition for protecting against the effects of Tumor Necrosis Factor (TNF), wherein said composition is obtainable from human amniotic tissue with apoptosis modulating activity.

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83. A method for protecting against the effects of Tumor Necrosis Factor (TNF) in a cell comprising contacting said cell with an effective amount of the composition of claim 82.

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84. A method for protecting against the effects of Tumor Necrosis Factor (TNF) in a subject comprising administering to the subject an effective amount of the composition of claim 82 to said subject.

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